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The Honorable Gregory M. Sleet
United States District Court
844 North King Street
Lock Box 19
Wilmington, DE 19801

RE: Talecris Biotherapeutics, Inc. and Bayer Healthcare LLC v. Baxter International, Inc. and Baxter Healthcare Corp., C.A. No. 05-349-GMS

Dear Judge Sleet,

Pursuant to Paragraph 8 of the Scheduling Order, Plaintiffs Talecris Biotherapeutics, Inc. and Bayer Healthcare LLC (collectively, "Talecris") submit this letter in opposition to Defendants Baxter International Inc. and Baxter Healthcare Corporation's (collectively, "Baxter") February 1, 2007 letter requesting permission to file multiple motions for summary judgment: (1) non-infringement of U.S. Patent No. 6,686,191 ("the '191 patent"); (2) invalidity of the '191 patent under 35 U.S.C. § 112 (written description); and (3) invalidity of the '191 patent under 35 U.S.C. § 112 (indefiniteness).

Baxter's defenses are laden with questions of material fact that cannot properly be resolved by summary judgment. The parties currently are in the middle of expert discovery. To date, Baxter's expert reports total over 600 pages while Talecris' expert reports total over 500 pages including voluminous sections on the very issues on which Baxter seeks permission to file summary judgment motions. The parties' experts materially disagree on these numerous issues including, but not limited to: the interpretation of data derived from samples relating to anticomplement activity ("ACA") levels; the validity and appropriateness of the assays used to measure ACA; the appropriateness of the experimental design to measure the increase of ACA; the application of the claims to the data in light of the Court's claim construction; and the scope, content, and meaning of the '191 patent pertaining to the written description and indefiniteness issues. These are all uniquely fact-sensitive inquiries which must be assessed against a backdrop of expert testimony. Each issue should be heard by a jury during the scheduled seven day trial in July, 2007. Very plainly, judicial and party resources will be unnecessarily wasted should the Court permit summary judgment briefing. Thus, Talecris respectfully requests that the Court deny Baxter's request to file multiple motions for summary judgment of alleged non-infringement, alleged invalidity based on lack of written description, and alleged invalidity based on indefiniteness.

I. INFRINGEMENT

The '191 patent generally claims a method of treating a solution of antibodies, which comprises a solvent/detergent ("S/D") step ("step (a)") that results in an increased level of ACA, followed by an incubation step ("step (b)"), which reduces the level of ACA to an acceptable level suitable for intravenous administration. The Court issued its claim construction ruling on December 28, 2006, rejecting Baxter's proposed constructions, and adopting the "plain and ordinary meaning" of most terms.

Apparently conceding that all other elements of claim 1 are met, Baxter argues that Talecris cannot prove that: "(1) Baxter's solvent/detergent treatment step 'increases' ACA; (2) Baxter's incubation step reduces the 'increased [ACA] of the solution'; or (3) Baxter's incubation step reduces ACA to 'an acceptable level.'" Baxter is wrong, and its arguments are replete with disputed factual inquiries. As Baxter stated to the Court at the claim construction hearing, "when you are talking about ACA, everything is complicated...." *See* Ex. 1 (Tr. From 12.14.06 *Markman* Hearing at 39). Despite the admitted complexity of the issue, Baxter now seeks to thrust the Court into this controversy without the benefit of expert testimony. This effort is misguided and inappropriate. It should be rejected.

A. Baxter's S/D Treatment "Increases" ACA.

Claim 1 requires that step (a) result in "an increased level of [ACA]." Talecris' experts tested samples from manufacturing lots of Baxter's Gammagard® Liquid product from various points along the manufacturing process. As an initial matter, the hemolytic assays and C1q assays, such as those used by Talecris' expert to measure ACA, are valid and appropriate. Baxter conceded this point for the purpose of summary judgment. Baxter contends that Talecris' assays and data do not show an increase in ACA. Talecris' expert has submitted a detailed report establishing that the data in fact show an increase, and he will testify accordingly. Subsidiary questions of fact include which samples should be used to determine whether there is an increase across step (a) and how the data are to be interpreted. Talecris' expert contends that the increase is determined between Samples 2 and 3 from the C1q assay, or in the alternative between Samples 2 and 5, and that all the ACA data consistently show an increase. Baxter's expert contends that the increase is only determined between Samples 2 and 5 and that not all of the data show an increase. Thus, there is a direct conflict between the experts, which should be resolved by a jury after hearing testimony.

B. Baxter's Incubation Step Reduces "The Increased ACA Of The Solution."

Step (b) of claim 1 requires "that the increased [ACA] of the solution" is reduced. Here again, the parties' experts disagree. Talecris' and Baxter's data clearly show an ACA reduction by reason of step (b). Moreover, the Court has construed this term to have its plain and ordinary meaning. Baxter's argument depends on rewriting the Court's claim construction and limiting claim 1 such that the ACA after S/D treatment must be exactly the same as the ACA of the solution before incubation. Such a reading of the claim ignores the Court's construction of the term "then incubating the solution of step (a)" which specifically allowed for additional processing steps between steps (a) and (b). Baxter attempts to insert this limitation because claim 1, as written, clearly encompasses their process. Regardless, the parties' experts will address the facts relating to these issues at trial.

C. Baxter's Incubation Step Reduces ACA "To An Acceptable Level."

Step (b) of claim 1 also requires that the "increased [ACA] of the solution is reduced to an acceptable level." Baxter argues that Talecris "cannot show Baxter's ACA was 'unacceptable' prior to incubation." Baxter's argument verges on the nonsensical because this Court has already rejected Baxter's claim construction argument that the ACA level must rise to an "unacceptable" level after the S/D treatment. The plain language of claim 1 requires only an ACA reduction and an acceptable ACA following that reduction. Whether Talecris' data show that the ACA of Baxter's Gammagard Liquid® product is reduced "to an acceptable level" is a material factual dispute between the parties. We note, however, that GAMMAGARD® Liquid 10% is currently approved and marketed for intravenous administration to human patients. Baxter does not (and arguably cannot) dispute that the ACA of its product must be "acceptable," as required by the claim, because it is commercially available for administration to patients.

II. WRITTEN DESCRIPTION

Whether a patent complies with the written description requirement is an issue of fact. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1324 (Fed. Cir. 2002) (citation omitted). The Federal Circuit has held that the written description requirement mandates that an applicant provide a description that "reasonably conveys" to one skilled in the art that the inventor was in possession of what is claimed as of the filing date sought. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991)(citation omitted). The applicant accomplishes this by using such descriptive means as "words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed.Cir. 1997). Further, while it is not necessary for the applicant to describe the claimed subject matter in the same terms as used in the claims, "the specification must contain an equivalent description of the claimed subject matter." *Id.* (citation omitted).

Baxter argues that "[c]laim 1 lacks sufficient written description with respect to the terms 'increased level of [ACA]' and 'the increased level of [ACA] of the solution'" because: (1) the '191 patent does not disclose data showing a "before and after" S/D treatment comparison of ACA; and (2) the '191 patent does not disclose the standard deviation or variation for the reported ACA values. The '191 patent was not required to show these things. The '191 specification clearly teaches an increase under exemplified S/D conditions. Numerous tables in the '191 patent disclose data that exemplify the claimed invention. Talecris' experts will confirm that the specification adequately describes the increase and will explain the assays and how the results derived from them should be interpreted.

The '191 claims do not, and need not, specify how the ACA increase is determined. One skilled in the art would know how to make this determination. Whether "parallel" or "before and after" experimental designs are appropriate to measure the increase in ACA and whether and how the characteristics of a particular assay influence these measurements are questions over which the parties disagree. Claim 1 states that the S/D treatment will be performed under conditions "*resulting* in an increased level of ACA." (Emphasis added). All that is required is causation. The '191 patent provides data, including data from a parallel experiment, to show the increase in ACA over the S/D step. This is more than sufficient to satisfy the written description requirement. Summary judgment is manifestly inappropriate given the facts of this case and the disagreement between the parties' experts.

III. INDEFINITENESS

A patent specification shall conclude with one or more claims that "particularly [point] out and distinctly [claim] subject matter which the applicant regards as his invention." 35 U.S.C. § 112, ¶ 2. Although compliance with § 112, ¶ 2 is a question of law, *see Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986), it rests on a factual determination of whether one skilled in the art would understand the bounds of the claim when read in light of the specification." *See Invitrogen Corp. v. Biocrest Mfg.*, 424 F.3d 1374, 1383 (Fed. Cir. 2005). As Baxter concedes, claims are indefinite "'if reasonable efforts at claim construction prove futile,' that is, if a claim 'is insolubly ambiguous, and no narrowing construction can properly be adopted.'" *Id.* (citation omitted). As long as the boundaries of a claim may be understood, invalidity for indefiniteness will be avoided. *Id.* Baxter contends that the terms "acceptable level suitable for intravenous administration", "increased level of [ACA]", "then incubating the solution of step a)", and "increased [ACA] of the solution" are indefinite. Baxter is wrong.

A. The Court construed "acceptable level suitable for intravenous administration" to have its plain and ordinary meaning. "[I]f a claim is subject to construction, *i.e.*, it is not insolubly ambiguous, it is not invalid for indefiniteness." *Bancorp Servs. L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1372 (Fed. Cir. 2004). That this Court was able to construe the term "acceptable level suitable for intravenous administration" proves that this term is not indefinite. *See e.g.*, *Mallinckrodt Inc. v. Masimo Corp.*, 2004 U.S. Dist. LEXIS 28518, at *69 (C.D. Cal. Jul. 12, 2004); *Intex Rec. Corp. v. Metalast, S.A.*, 2005 U.S. Dist. LEXIS 10147, at *30-31 (D.D.C. May 20, 2005). In fact, the Court stated that this term, as with most of the construed terms, should be accorded "its plain and ordinary meaning." Baxter repeats the same now discredited argument it made on claim construction. The Court, having considered both parties' arguments, specifically rejected Baxter's suggestion to narrow the scope of the claims. Surely, the fact that the Court found this term so plain and ordinary on its face that it did not require a narrowing construction established that this term is not "insolubly ambiguous." Baxter, however, argues this claim term is indefinite because: "(1) there was, and is, no single level of 'acceptability' for ACA; (2) an assay (test) must be validated for a particular product for the ACA value obtained with that test to make sense; (3) ACA values obtained using different assay cannot be compared; and (4) ACA values cannot be correlated to adverse events in humans."

Baxter's assertions raise a number of factual disputes. First, the parties have offered conflicting expert testimony over whether one of ordinary skill in the art would understand the bounds of the claim. Second, whether there is a relationship between ACA and adverse events is also a fact issue that should be heard by a jury. Baxter has not presented testimony from any medical doctor. Third, whether a "skilled artisan in 1995 would have known that ACA values cannot necessarily be correlated to adverse events in humans" is an issue of fact, which is informed by expert testimony.

B. Baxter argues that "increased level" and "reduced to an acceptable level suitable for intravenous administration" are indefinite because "[a]ssuming Plaintiffs are correct that the patent does not require an 'increase' in ACA to an unacceptable level, the subsequent claim term 'reduced to an acceptable level' has no meaning since the ACA level before incubation could already be 'acceptable.'" Baxter further argues that "[i]t would be nonsensical to reduce ACA from an 'acceptable' level to an 'acceptable' level...." The Court has construed these terms to

have their plain and ordinary meaning, and again, for the reasons stated *supra*, this defeats Baxter's indefiniteness argument. The '191 patent is directed to a method of reducing increased ACA to a level suitable for intravenous administration. The Court has already rejected the argument that the increase needs to be to an "unacceptable" level. Moreover, the specification states that "IGIV preparations should have ACA levels as low as possible." '191 patent, col. 5, ll. 54-55. Thus, reducing the elevated ACA to an "acceptable" level, while another issue for the jury to resolve, is all that the claim requires.

C. Baxter next argues that the terms "then incubating the solution of step a)" and "increased [ACA] of the solution" are indefinite. The Court construed "increased [ACA] of the solution" to have its plain and ordinary meaning. The Court construed the term "then incubating the solution of step a)" to mean "incubating a solution originating from step a) under conditions of controlled time, pH, temperature, and ionic strength, wherein additional steps may be performed prior to said incubating." Baxter argues "[b]ecause the additional processing steps allowed by the claim would result in a different 'solution' with a different ACA level being incubated; it would no longer be 'the increased ACA of the solution' as required by step (b)." However, there is no requirement in the claims that the ACA immediately preceding the step b) incubation be exactly the same as the level immediately following the S/D step. Moreover, there can be no difference between these intermediate "solutions" (*i.e.*, "the solution of step a)" and "the solution" which has the "increased [ACA]") since, in accordance with the Court's claim construction, these intermediate solutions *are* "the solution of step a)" because they originate from step a). Thus, these terms are not indefinite, and in any event, the continuing disagreement between the experts raises factual questions to be decided by a jury.

IV. CONCLUSION

The proper forum in which to resolve unresolved factual issues is at trial, not a summary judgment. *Armco, Inc. v. Cyclops Corp.*, 791 F.2d 147, 151 (Fed. Cir. 1986)(reversing summary judgment decision where there was evidence provided on both sides of the issue and the district court resolved disputes of material fact in coming to its conclusion). "Though speedy and inexpensive, summary judgment is nonetheless a 'lethal weapon' capable of 'overkill'. It denies the non-movant its 'day', *i.e.* a trial, in court. Moreover, experience has shown that a trial often establishes facts and inferences not gleanable from papers submitted pre-trial." *Sri Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1116 (Fed. Cir. 1985)(citations omitted). For the foregoing reasons, Talecris respectfully requests that the Court deny Baxter's request for permission to file multiple motions for summary judgment on alleged non-infringement and alleged invalidity based on written description and indefiniteness of the '191 patent. The record in this case and the inherent nature of these issues render summary adjudication highly inappropriate and, quite simply, a waste of the Court's time.

Respectfully submitted,

/s/ Jeffrey B. Bove

JBB/dkh

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